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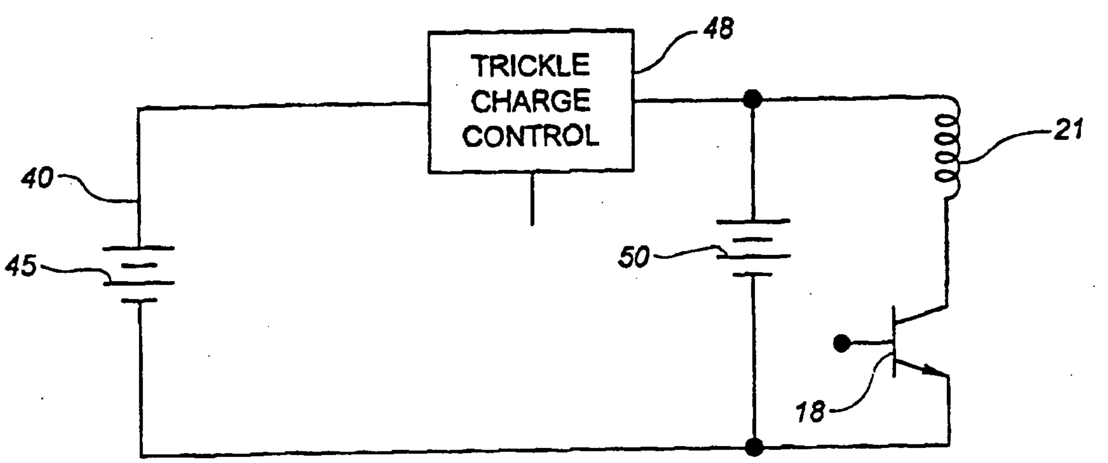

(57) Abstract

A staged energy storage system (40) provides electrical energy to an implantable cardioverter defibrillator device by using the combination of a first stage energy source (45), and a second stage energy concentration system (50). The second stage energy concentration system (50) allows for either a lower density and/or lower voltage energy source to be used as the first stage energy source (45), thereby decreasing the battery cost, size and weight, or alternatively, for multiple closely spaced countershock pulses to be delivered. In one embodiment, the second stage energy concentration system (50) comprises a rechargeable battery (50). In another embodiment, the second stage energy capacitor system (50) comprises a high energy density capacitor system.

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STAGED ENERGY STORAGE SYSTEM FOR IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR

Field of the Invention

This invention relates to the energy storage systems for implantable biomedical devices, and more particularly, to the energy storage systems for implantable cardioverter-defibrillators employing high voltage capacitive discharge outputs.

Background of the Invention

Implantable biomedical devices typically do not have large current requirements so as to maximize the overall useful battery life and minimize the size of the battery required to power such devices. A good example of such a lower power biomedical device which utilizes only microwatts of power is a pacemaker. More recently, however, implantable biomedical devices have been developed which have higher power requirements, often in the milliwatts to watts range. Consequently, there has been a need to develop better energy storage systems for these devices.

A good example of an implantable biomedical device which has a higher power output requirement is an implantable cardioverter-

defibrillator. Cardiac defibrillation in humans using an implantable cardioverter-defibrillator requires the delivery of an electrical pulse that is several milliseconds long with peak currents as high as 25 amperes. The total energy in such a pulse can be as high as about 30 Joules. In order to deliver such a high current, a high voltage defibrillation capacitor system is charged up to a voltage on the order of about 750 volts using a transformer powered by a low voltage battery. Once charged, the capacitor system is ten selectively discharged through at least a pair of implantable electrodes in the form of a defibrillation/cardioversion countershock.

Various special batteries have been developed to supply such a high current to the transformer in order to charge the high voltage defibrillation capacitor of an implantable cardioverter-defibrillator. However, the batteries used for existing implantable cardioverter-defibrillators comprise relatively low energy density batteries (about 500 J/gram) which occupy a relatively large volume within the device. In addition, these special batteries are very expensive and most implantable cardioverter-defibrillators require the use of two such battery cells. In implantable cardioverter-defibrillator devices, the combined volume of the battery and the high voltage defibrillation capacitor(s) is greater than the electronics. Therefore, any reduction in battery cost, size or weight can provide significant enhancements to an implantable cardioverter-defibrillator.

Summary of the Invention

A staged energy storage system provides electrical energy to an implantable cardioverter-defibrillator device by using the combination of a first stage energy source and a second stage energy concentration system. The second stage energy concentration system allows for either a lower density and/or lower voltage energy source to be used as the first stage energy source, thereby decreasing the battery cost, size and weight, or, alternatively, for multiple closely spaced countershock pulses to be delivered. In one embodiment, the second stage energy concentration

system comprises a rechargeable battery. In another embodiment, the second stage energy capacitor system comprises a high energy density capacitor system.

In accordance with the present invention, a staged energy storage system is provided for an implantable cardioverter-defibrillator. The implantable cardioverter-defibrillator is comprised of a biocompatible housing containing a sensing system for sensing cardiac dysrhythmias, a high voltage discharge capacitor system, a transformer and a control system for selectively charging the capacitor system and then discharging the capacitor system through a plurality of implantable electrodes in response to the sensing of a cardiac dysrhythmia. The staged energy storage system provides low-voltage energy to the transformer and is characterized in that the staged energy storage system includes: a first stage energy source means for providing a low-voltage electrical current; a second stage energy concentration means for storing the electrical current delivered from the first stage energy source means; and means for selectively discharging the electrical current in the second stage energy concentration means to the transformer as at least one short-term, low-voltage, high-current discharge of greater than 0.5 A.

In accordance with a first aspect of the present invention, the first stage energy source means comprises a low-current battery having an output current of less than 10 mA, and the second stage energy source means is rechargeable so as to eliminate the need for a non-rechargeable, high-current battery.

In accordance with a second aspect of the present invention, the first stage energy source means comprises a non-rechargeable, high current battery having an output current of at least 1A, and the second stage energy source means is rechargeable so as to allow for the delivery of multiple closely spaced electrical countershocks within one second of each other.

Brief Description of the Drawings

Figure 1 is a simplified circuit diagram of a prior art implantable defibrillator circuit.

Figure 2 is a simplified schematic circuit diagram of a staged energy concentration circuit.

Figure 3 is a simplified schematic circuit diagram of an alternate embodiment staged energy concentration circuit.

Figure 4 is a simplified schematic circuit diagram of an alternate embodiment staged energy concentration circuit.

Figure 5 is a simplified schematic circuit diagram of a staged energy concentration circuit using a concentration capacitor system.

Figure 6 is a schematic circuit diagram of a staged energy concentration system for delivery of a rapid pulse sequence.

Figure 7 is a schematic circuit diagram of an alternate embodiment of a staged energy concentration system for delivery of a rapid pulse sequence.

Detailed Description of the Invention

Figure 1 is a simplified circuit diagram of a known implantable defibrillator circuit 10. Circuit 10 comprises a high current defibrillation battery 13, which is typically a low energy density lithium silver vanadium oxide (SVO) battery. A high voltage transformer 15 comprises a transistor switch 18 which drives the primary 21. The oscillator driving switch 18 provides an alternating current through the primary of transformer 15. The secondary 25 of transformer 15 produces a significantly higher voltage which is rectified by diode 27 and stored in high voltage defibrillation capacitor 30. When high voltage defibrillation capacitor 30 is fully charged, the semiconductor switch 32 is activated to complete the circuit which delivers the charge of high voltage defibrillation capacitor 30 to the cardiac electrodes 35 for defibrillation or cardioversion of the heart. A configuration which is similar to the above circuit comprises substitution of a H-bridge in place of switch 32. This permits delivery of the current

from high voltage defibrillation capacitor 30 in either polarity, which allows delivery of a biphasic pulse. It will be appreciated that numerous variations to the monitoring, control and capacitor configurations of circuit 10 are known in the art and are equally possible with the present invention, as shown for example in U.S. Patents Nos. 5,199,429, 5,306,291, 5,312,443, 5,334,219 and 5,372,605.

Generally, circuit 10 works well in cardiac defibrillators; however, the SVO batteries have an energy storage density of only 500 joules per gram (J/g). This is due to the tradeoff between energy storage capability and current delivery capability. In contrast, the battery chemistry of the well known Lithium Iodide (LiI) pacemaker battery has approximately twice the energy storage density of the SVO battery, or about 1000 J/g. This means that implantable defibrillator devices using a SVO battery are utilizing a battery with a mass that is twice the mass required if a LiI pacemaker battery were used. Use of a LiI battery alone in an implantable defibrillator has not been possible because a LiI battery can delivery of only very small currents, on the order of milliamperes. As disclosed in U.S. Patent No. 5,372,605, it is possible to solve this problem by using an LiI battery to power just the monitoring and integration circuits and related sub-systems, and using a separate SVO battery system to charge the high voltage defibrillation capacitor sub-system. Alternatively, power to the monitoring integration circuits and related sub-systems may be advantageously provided by a high-energy-density Li-CFx battery.

Figure 2 discloses a simplified schematic staged energy circuit 40. Circuit 40 comprises a first embodiment of an improved staged energy concentration means designed for replacing that portion of circuit 10 denoted as primary sub-circuit 42 in Figure 1. Circuit 40 preferably comprises a first stage of energy concentration comprising a non-rechargeable battery, such as a high energy density pacing battery 45, configured for applying a small microampere current to the trickle charge control circuitry 48. This provides an optimum current to be supplied to a second stage of energy concentration, comprising either a rechargeable

battery 50 as discussed in reference to Figure 2, or a low voltage, high energy density second stage concentration capacitor system 69 as discussed in reference to Figure 5.

In the embodiment shown in Figure 2, the rechargeable battery system preferably comprises a rechargeable defibrillator battery 50 that is maintained fully charged by the pacing battery 45. Rechargeable defibrillator battery 50 is used to drive primary 21 of the high voltage transformer, or similar power transfer means, through a switch 18 in a manner similar to conventional circuits, such as circuit 10.

The staged energy concentration configuration of circuit 40 permits use of high density pacing batteries to store energy in combination with a very small rechargeable defibrillator battery to deliver a high current for somewhere between about 5 shocks. A typical defibrillator will deliver about 200 defibrillator shocks. Assuming each of the shocks is of 30 J, and assuming transformer losses of 25%, the energy system of a conventional implantable defibrillator must store at least 200 x 40 J = 8000 J. Because all of this energy is stored in a single lower density SVO battery having an energy density of 500 J/gram, a total of at least 16 grams is required for battery system for a conventional defibrillator. Due to the staged energy arrangement of the present invention, the second stage energy concentration system need only store enough energy for a typical cardiac defibrillation session of about 5 shocks. As a result, the second stage of energy concentration must therefore only store about 5 x 40 J = 200 J. In the embodiment of the rechargeable battery 50 as the second stage system, the 8000 J of energy can be stored in a high density LiI battery at 1000 J/g, for only about 8 grams with about an additional 1-2 grams required for the lower density rechargeable battery.

Alternatively, a high-energy-density Li-CFx battery capable of storing up 1600 J of energy per gram of battery mass may be used as the second stage system. Using such a battery, is possible to store the needed 8000 J of energy in a mass of only about 5 grams, along with the additional 1-2 grams of mass needed for the lower density rechargeable battery. A

comparison of the characteristics of Li-CF_x batteries relative to LiI batteries is presented below in Table 1.

TABLE 1

Titanium Li-CFx / Li-Iodine Comparison

	LiCFx	**LiI**
Deliverable Capacity (100kΩ)	1200 mAh	1250 mAh
OCV	3.3.V	2.78 V
Pulse Amplitude (typical)	20 mA	100 μA
Impedance (1 kHz @ 0.9 Ah)	6-7 Ω	≈ 1000 Ω
Impedance (1 kHz @ 1.1 Ah)	< 20 Ω	≈ 4000 Ω
Weight	7.6 g	14.4 g
Volumetric Energy Density	0.9 Wh/cc	0.9 Wh/cc
Gravimetric Energy Density	1600 J/g	850-1000 J/g
Operating Temp. Range	-20 to +55° C	37° C
Cell Swelling (typical)	< 5%	15 to 25%
Self-Discharge	< 1%/yr	2 -4 %/yr

The total mass of the staged energy storage system of the present invention, including the mass of the first stage energy storage (8 grams) and the mass of the second stage energy concentrator (1-2 grams), is almost one-half the mass of a conventional single stage energy storage system (16 grams). The total mass of such a system would be on the order of 7 grams, including 5 grams for the Li-CFx battery, and 1-2 grams for the second stage concentrator, resulting in a savings of over half of the mass of current systems. Equally as important, the expense of the staged energy storage system of the present invention is significantly reduced as two SVO's are typically used for conventional energy storage in existing implantable defibrillators and the cost of a SVO battery that stores 4000 J is more than ten times that of a rechargeable battery or low voltage, high density capacitor system that could store the 200 J required for the second stage energy concentration required by the present invention. In addition to the

LiI and Li-CF_x batteries discussed above, other low current, high energy density batteries capable of providing significant advantages over SVO cells include radioisotope-activated batteries, such as shown in U.S. Patents Nos. 3,767,947, 4,628,143 and 5,000,579, nuclear batteries, such as shown in U.S. Patents Nos. 3,094,634, 3,740,273, 4,024,420 and 4,835,433, or thermoelectric batteries, such as shown in U.S. Patents Nos. 4,002,497 and 4,026,726.

Although the amount of energy required to be stored by the second stage of energy concentration is relatively small, always less than 1000 J and typically less than 500 J, the second stage must be able to deliver a fairly high current of at least 0.5 A, and preferably about 1-2 A. Representative rechargeable battery chemistries having single battery cells that are capable of meeting these specifications for high current delivery are shown in Table 2.

TABLE 2

Second Stage Batteries

Chemistry	Average Cell Voltage
$LiMoS_2$	1.85
$LiMnO_2$	3.0
LiV_2O_5	2.8
$LiTiS_2$	2.2
LiV_6O_{13}	2.3
$LiCuC_{12}$	3.2
$LiSO_2$	3.1
LiCFx	3.3
NiCad	1.2
Alkaline	1.5
Lead acid	2.0

Figure 3 discloses another embodiment of the staged energy concentration invention. Circuit 60 discloses a single cell pacing battery 63

which is used to power a voltage doubler circuit 67. This doubler circuit 67, which comprises numerous embodiments as described, for example, in 5,372,605, may be configured to produce an output of approximately 6 volts for charging a rechargeable defibrillation battery, such as battery 70.

Another embodiment of a staged energy concentration defibrillator circuit is shown in Figure 4, in which circuit 76 comprises first stage battery 80. Battery 80 is a low voltage, for example a 2.8 volt, LiI single cell battery which charges two second stage batteries 83 and 84. Batteries 83, 84 are preferably Lithium Titanium Disulfide ($LiTiS_2$) batteries. Preferably, battery 84 is charged through diode 86, battery 83 is charged through diode 87, and resistor 89 is used with a preferred value of 10K ohms. Field effect transistor switch 92 is off during this time. It is recognized that this schematic circuit is further simplified because there is optimal trickle charge current limiting between battery 80 and the two diodes 86, 87, however, that detail is not considered important to this depiction of the invention.

When fibrillation is detected by related detection circuitry, it is then time to charge the defibrillation capacitor(s) and switch 92 is turned on. That places batteries 83 and 84 in series, providing a voltage of approximately 5 volts for the transformer primary 21. As above, oscillating switch 18 is used to cause a pulsating current to pass through primary 21 of the transformer.

Use of a multi-stage energy storage system, as disclosed in the present invention, provides great savings in both volume and weight of an implantable biomedical device. For example, because the existing defibrillator battery chemistry has about half the density of the pacing battery, it is possible to reduce the total battery weight of an implantable cardioverter-defibrillator by greater than about 50% by allowing for the use of a higher energy density battery as the primary energy storage system and relying on the second stage energy concentration as taught by the present invention to actually charge the defibrillation capacitors of the implantable cardioverter-defibrillator. This provides dramatic improvement in the

manufacture, implantation, and operation of the defibrillator, particularly in view of the restricted size of desired pectoral implant sites.

In either configuration, it is advantageous to provide a rechargeable second stage concentration that permits rapid charging of the defibrillator capacitor means. Indeed, in certain configurations it is possible to recharge at a rapid 3-5 second rate using the two stage charging system of the present invention, rather than at a slower rate of 12-15 seconds which is common in the industry. Therefore, yet another advantage of this invention derives from the use of the second stage energy concentration as a recharge rate accelerator. This also results in a defibrillator with reduced end of life charge degradation due to the constantly recharged second stage. This feature effectively provides a battery life extension capability before elective replacement, assuming certain accepted energy levels.

In the embodiment shown in Figure 5, a low voltage, high energy density second stage concentration capacitor system 69 is used in place of rechargeable defibrillation battery 50 as shown in Figure 2. Second stage concentration capacitor system 69 is used to drive the primary coil 21 of high voltage transformer 15 through the use of oscillator driven switch 18. The secondary side 25 of high voltage transformer 15 charges defibrillation capacitor 30 through the rectifying diode 27. The remaining portion of circuit 40 operates in a manner similar to circuit 10 as described in Figure 1.

As with Figure 5, a trickle charge control circuit 48 controls the charging of concentrations capacitor system 69 from non-rechargeable battery 45. Trickle charge control circuit 48 is of conventional design and may include a voltage step-up feature as described for example, in U.S. Patent No. 5,372,605. The voltage step-up feature is preferably included to counteract a decrease in the efficiency of high voltage transformer 15 at lower voltages as concentration capacitor system 69 discharges. For example, if non-rechargeable battery 45 is a 2.2 V LiI battery, trickle charge control circuit 48 would include a 5x1 voltage step-up to yield a total of 11 V across concentration capacitor system 69. As a result, 75% of the energy transfer from concentration capacitor system 69 to high voltage

transformer 15 will occur at a voltage of 5.5 V or higher. Alternatively, a single SVO 3.0 V cell could be used with a 4x1 voltage step-up, for example. In the former case with the LiI battery, the resulting energy storage system would have more total stored energy (8000 J), but would take several hours to fully recharge concentration capacitor system 69 after delivery of a complete set of countershocks. In the later case with the SVO battery, the resulting energy storage system would have less total stored energy (4000 J), but would be able to quickly recharge concentration capacitor system 69 in less than a minute. Because the concentration capacitor system 69 would serve as buffer to maintain optimum transfer characteristics across high voltage transformer 15, the later example would have the significant advantage of saving the cost of a second SVO cell, as compared to energy storage systems for existing implantable cardioverter-defibrillators.

An alternative embodiment of the later case would allow concentration capacitor system 69 to be used together with the SVO battery and the 4x1 voltage step up to jointly produce the voltage across primary coil 21 of high voltage transformer 15. It would be possible, for example, to make a single cell SVO battery arrangement more efficient if, instead of trying to take all 30 J from the SVO cell, 15 J was taken from the SVO cell through the step up circuit and the other 15 J was taken from 30 J stored in two dual layer capacitors. Total net energy requirements for such a system would be 8 grams for the SVO cell and 4 grams for the dual layer caps occupying only an additional 3 cc. Alternatively, the dual layer capacitors could be used provide power to the circuitry of the implantable cardioverter-defibrillator while the SVO cell is charging the main energy delivery capacitor. In this arrangement, the use of a single dual layer capacitor would prevent undesirable low voltage spikes from resetting the internal circuitry of the implantable cardioverter-defibrillator during the charging of the main energy capacitor.

Second stage concentration capacitor system 69 is preferably comprised of one or more double layer capacitors having no permanent dielectric, although it would be possible to use an electrolytic capacitor,

provided the electrolytic capacitor had a sufficient energy density rating. Currently available capacitor technology is capable of producing a double layer capacitor with a maximum voltage rating of 11 volts and a maximum energy density of around 10.7 J/cc. An example of such a double layer capacitor is the Panasonic SG. Other possible dual layer capacitors useful with the present invention include the Ruthenium Oxide (RO) dual layer capacitor developed by Pinnacle Research Co. New manufacturing technologies and materials are being introduced for double layer capacitors which have the potential to increase the capacitance and voltage ratings of these devices. These improvements involve new materials with increased surface areas (which directly relates to capacitance), and new manufacturing techniques to reduce the space between the plates which decreases both the overall resistance and the overall size of the capacitor.

Using the example previously set forth, assume that the implantable cardioverter-defibrillator must be capable of delivering 5 countershocks, each of 30J. In the case of the concentration capacitor system 69 as the second stage system, only one-half of the electrical voltage found in the capacitor system will occur across the load (in this case the primary coil 21 of high voltage transformer 15) assuming maximum energy transfer conditions exist due to load matching between the capacitor system and the load. As a result, when the concentration capacitor system 69 is used as the second stage system of the present invention, it must store 5 x 80 J = 400 J for operation equivalent to rechargeable battery 50.

A set of calculations can be established to determine, for a given delivered energy/countershock and number of countershocks/therapy regimen, the appropriate configuration for concentration capacitor system 69. Because of the 50% loss for load matching and the 25% loss across transformer 15, the energy required (E_{req}) for second stage concentration capacitor system can be stated as follows:

$$E_{req} = ((E_{del} / L_{tran}) / L_{load}) * N \qquad (1)$$

where E_{del} is the desired maximum energy to be delivered by a countershock, L_{tran} is the 1/transformer efficiency, L_{load} is 1/loss due to load matching and N is the desired number of countershocks in a therapy regimen. Assuming that the individual dual layer capacitors that makeup concentration capacitor system 69 are arranged in series, then:

$$V_{tot} = V_1 + V_2 + \ldots V_n = V * n \qquad (2)$$

$$1/C_{tot} = 1/C_1 + 1/C_2 + \ldots 1/C_n = 1/C * n \qquad (3)$$

$$ESR_{tot} = ESR_1 + ESR_2 + \ldots ESR_n = ESR * n \qquad (4)$$

For a capacitive discharge energy transfer, assuming no losses, the delivered energy is given by the classic equation:

$$\begin{aligned} E_{del} &= .5 * C * V^2 \qquad (5) \\ &= .5 * C / n * (V * n)^2 \end{aligned}$$

solving Eq. (5) for the number (n) of dual layer capacitors required for a given delivered energy yields:

$$n = (2 * E_{del}) / (C * V^2) \qquad (6)$$

using Eqs. (1) and (6) to solve for the number (n) of dual layer capacitors required for a given delivered energy, transformer efficiency, load loss and therapy regimen yields:

$$n = (2 * N * E_{del}) / (L_{tran} * L_{load} * C * V^2) \qquad (7)$$

Substituting for a 40 J countershock, a 75% transformer efficiency, a 50% load efficiency and a 5 countershock therapy regimen into Eq. (7) and

solving, for example, for the dual layer Panasonic SG capacitors, each having ratings of:

Capacitance	= 1F
Voltage	= 5.5 V
ESR	= 30 Ω
Volume	= 1.42 cc
Weight	= 2 grams
E_{std}	= 15.25 J

the minimum number (n) of such dual layer capacitors required would be 27. While this large number of capacitors for existing dual layer capacitors does not make such an arrangement a particularly attractive alternative to energy supply systems for existing implantable devices, there are other arrangements which do make the concentration capacitor system 69 an attractive alternative. For example, when a SVO battery is used, the number of countershocks in a therapy regimen can be reduced to 1 because the battery can recharge concentration capacitor system 69 between countershocks. As such, the total number of such capacitors required would be only 6, a realistic tradeoff even with existing dual layer capacitor technology to reduce the cost of the implantable device. Alternative, if the effectiveness of the countershock waveform is increased so that the maximum delivered energy/ countershock can be decreased to, for example, 16 J, then the total number of capacitors required would be cut in half. This value could be reduced still further if the therapy shock regimen were set to a smaller value than 5 shocks.

An excellent example of a potential use of the staged energy concentration power supply system of the present invention is for a prophylactic implantable cardioverter-defibrillator similar to that described in U.S. Patent No. 5,439,482. For example, a prophylactic implantable defibrillator with a total energy budget of 4000 J could be provided with a three-shock therapy regimen for a budgeted number of 50 regimen cycles,

each of the countershocks in a therapy regimen cycle having a maximum delivered energy of 10 J, 10 J and 20 J, respectively. In this situation, the total energy required to be stored in concentration capacitor system 69 would be about 105 J, an energy level which can be achieved by 7 individual dual layer capacitors utilizing existing capacitor technology, that together would occupy about 9.75 cc and weigh about 14 grams. When combined with a 4000 J single cell LiI battery (4 cc and 8 grams), the overall volume of the energy storage system for this prophylactic defibrillator (total volume < 13 cc) is somewhat less than existing volumes of 16 cc for dual cell SVO battery systems, and the mass (total mass < 18 grams) is almost one-half of the mass for a 32 gram dual cell SVO battery system. Most importantly, however, the cost of such an energy storage system for an implantable device will decrease from almost $1000 to less than $50.

Another example of a use of a potential use of the staged energy concentration power supply system of the present invention is for the delivery of multiple closely spaced countershock pulses. Current medically accepted practice requires a minimum amount of energy for each countershock pulse delivered by a implantable cardioverter-defibrillators on the order of about 20-30 Joules. In contrast to such single pulse countershocks, electrical countershocks consisting of multiple pulse waveforms delivered closely together have been proposed which would likely lower the total defibrillation threshold by about 50 percent, cutting the 30 Joule accepted limit to about 15 Joules per pulse. However, such a system requires multiple sizeable main energy delivery capacitors. No disclosure exists for either a method or structure to achieve multiple closely spaced pulses using an intermediate power intensifier as disclosed below. The present invention teaches means for overcoming the impediments of such theoretical multiple pulse systems. The invention also discloses novel means for providing a rapid pulse power system for use with conventional ICD circuits to permit optional prompt transition from a widely spaced defibrillation pulse sequence to a closely spaced defibrillation pulse sequence.

The energy generation problem is appreciated more fully by calculating the charging power required of a representative main energy delivery capacitor system in an ICD device. Assuming a conventional single pulse defibrillator which is designed to deliver a 30 Joule pulse, a 10 second delay for capacitor charging is considered acceptable after fibrillation is detected. The charging power is described by simple calculation of 30 Joules divided by 10 seconds, which yields 3 watts. This 3 watt level of power is available from high quality defibrillation primary cells, such as lithium silver vanadium pentoxide cells, although others may be suitable.

Assuming a use of two closely spaced pulses, however, defibrillation could occur with 15 Joules in each pulse. The main energy delivery capacitor could be designed to store only 15 Joules and could be made of only half the size of present capacitors. However, although the main energy delivery capacitor has 10 seconds to charge in order to create the first pulse by use of present circuitry, the main energy delivery capacitor then must be quickly recharged to provide the second pulse. Generally, the amount of time required to quickly recharge is the same time as that required for optimum spacing between the two pulses, which is about 0.25 seconds. Therefore, the charging power must be equal to 15 Joules divided by 0.25 seconds. This requires a 60 watt power source. Currently, there is no functional implantable battery which is capable of providing such power output.

Figure 6 discloses the essential circuit elements of one embodiment of the present invention in which circuit 167 uses both a primary battery and an intermediate power intensifying system, with the latter comprising a very high power output system to provide the high charging power between capacitor pulses which can be either a power intensify battery or a power intensifying capacitor system. As shown, battery 170 is a low amperage primary defibrillation cell, which is preferably a lithium silver vanadium pentoxide type, although other materials are feasible. When fibrillation is detected, battery 170 is used to quickly charge a intermediate

power intensifying system 174 which is capable of very high power output. This is preferably accomplished through the use of transistor switch 176. Power intensifying system 174 is preferably selected from a list of possible high power, rechargeable batteries, such as lithium titanium disulfide, lithium sulfur dioxide, or other suitable for producing the desired power in a rechargeable configuration, or from a list of possible high energy density capacitors, such as dual layer capacitors. When power intensifying system 174 has been sufficiently charged then it is useful as a source of high current charging power to capacitor 132 in circuit 167 of Figure 6.

In the case where power intensifying system 174 is a high energy capacitor system, the capacitors are preferably comprised of one or more double layer capacitors having no permanent dielectric. Currently available capacitor technology is capable of producing a double layer capacitor with a maximum voltage rating of 11 volts and a maximum energy density of around 10.7 J/cc. Examples of such a double layer capacitor are the Panasonic SG and NEC FE capacitors. Other possible dual layer capacitors useful with the present invention include the Ruthenium Oxide (RO) dual layer capacitor developed by Pinnacle Research Co. New manufacturing technologies and materials are being introduced for double layer capacitors which have the potential to increase the capacitance and voltage ratings of these devices. These improvements involve new materials with increased surface areas (which directly relates to capacitance), and new manufacturing techniques to reduce the space between the plates which decreases both the overall resistance and the overall size of the power intensifying capacitor. Low impedance dual layer capacitors, for example, are the subject of intensive research and development in providing power supply systems for electrical cars and the advantages gained in that area could be applied to create a custom made optimized device for use in connection with the present invention.

In the case of a capacitor-based power intensifying system 174, the critical value of the dual layer capacitor system is the power transfer capability of the system. In order to deliver the second 10 J "half" of a total

20 J countershock, for example, power intensifying system 174 must be capable of transferring 13.3 J to the primary coil 121 of transformer 115 within less than 250 ms, assuming that the transformer has a 75% transfer efficiency. With these time and energy constraints, the power required of power intensifying system 174 is equal to:

$$\begin{aligned} P &= E / t \\ &= (13.3\,\mathrm{J}) / (250\,\mathrm{ms}) \\ &= 54\,\mathrm{W} \end{aligned}$$

In addition, the time constant of the power intensifying system 174 for maximum power transfer must be such the required energy is transferred to the primary coil 121 within a time constant $\tau = (RC)$ of less than 250 ms, where C is the effective capacitance of power intensifying system 174 and R is the equivalent series resistance (ESR) of power intensifying system 174. At present, applicants are not aware of any dual layer capacitors which would meet these specifications, however, existing commercially available dual layer capacitors, such as the NEC FE, are within range of meeting these specifications, and the development of newer, more efficient dual layer capacitors should make the present invention practical as well. The key is to have a low impedance dual layer capacitor with an ESR of less than about .25 Ω, as compared to existing high impedance dual layer capacitor systems with ESRs of greater than .5 Ω, and often greater than 10 Ω. The NEC FE dual layer capacitor, for example, has ratings of

Capacitance	= 1.5 F
Voltage	= 5.5 V
ESR	= .6 Ω
Volume	= 28.3 cc
Weight	= 20 grams
E_{std}	= 22.5 J

$P = 50.4\ W$

A preferred dual layer capacitor system ideally suitable for use with the present invention, for example, would consist of a dual layer capacitor having ratings of:

Capacitance	= 2 F
Voltage	= 5.5 V
ESR	= .1 Ω
Volume	= 15 cc
Weight	= 15 grams
E_{std}	= 30.25 J
P	= 121 W

The difference between the capacitor charging circuitry of Figure 6 and Figure 1 is an approximately 18:1 - 20:1 charging power ratio of 54 - 60 watts rather than 3 watts. The charging circuitry shown as schematic circuit 167 provides power means for recharging the capacitor of the related ICD device, after an initial discharge, between subsequent multiple pulses. This eliminates the need for additional main energy delivery capacitors and eliminates about half of the capacitor volume of known ICD devices. The invention also results in significant improvement in size and operation of an ICD device.

An alternate embodiment for charging power intensifying system 174 after fibrillation is detected comprises maintaining power intensifying system 174 substantially charged at all times. This may be accomplished by a variety of methods, including using primary battery 170 to provide a continuous nominal charge to power intensifying capacitor system 174, which is a recharging technique similar to that previously disclosed.

Another alternate embodiment for charging power intensifying system 174 after fibrillation is detected is disclosed in Figure 7. In this embodiment, circuit 190 comprises a relatively low amperage, e.g.

milliamps, primary defibrillation battery 193. One example of such a battery 93 comprises a pacing type lithium iodide battery. Other low current, high energy density batteries would include radioisotope-activated batteries, such as shown in U.S. Patents Nos. 3,767,947, 4,628,143 and 5,000,579, nuclear batteries, such as shown in U.S. Patents Nos. 3,094,634, 3,740,273, 4,024,420 and 4,835,433, or thermoelectric batteries, such as shown in U.S. Patents Nos. 4,002,497 and 4,026,726. Circuit 190 also comprises high power output (approximately 1-3 amperes) intermediate power concentration system 197. A preferred power intensify system 197 would comprise a rechargeable battery, such as lithium titanium di-sulfide battery or other lithium batteries, alkaline batteries, NiCad batteries or lead acid batteries, or a conventional high impedance dual layer capacitor. Power intensifying system 101 comprises a very high amperage (10-30 amps) battery, or a high power, low impedance dual layer capacitor. In operation, circuit 190 allows continuous trickle charge from battery 193 to power concentration system 197. This maintains power concentration system 197 in a substantially fully charged configuration until detection of fibrillation. After detection of fibrillation, power concentration system 197 simultaneously charges the main energy delivery capacitor 132 within sub-section 182 and power intensifying system 101, via switch 105. Capacitor 132 then discharges and is again re-charged with power concentration system 197. However, power concentration system 197 is not normally able to fully charge capacitor 132 in less than at least about 5 seconds. In a closely spaced multiple pulse ICD device power system it is necessary to provide means other than power concentration system 197 to provide charging power for subsequent pulses to the heart. Rather than providing multiple charging pathways or a plurality of capacitors, circuit 190 discloses use of power intensifying system 101 to provide high amperage high power means for charging a main energy delivery capacitor for countershock pulses after the initial countershock/pulse.

Claims

1. A staged energy storage system for an implantable cardioverter-defibrillator comprised of a biocompatible housing containing a sensing system for sensing cardiac dysrhythmias, a high voltage discharge capacitor system, a transformer and a control system for selectively charging the capacitor system and then discharging the capacitor system through a plurality of implantable electrodes in response to the sensing of a cardiac dysrhythmia, wherein the staged energy storage system provides low-voltage energy to the transformer and is characterized in that the staged energy storage system includes:

a first stage energy source means for providing a low-voltage electrical current;

a second stage energy concentration means for storing the electrical current delivered from the first stage energy source means; and

means for selectively discharging the electrical current in the second stage energy concentration means to the transformer as at least one short-term, low-voltage, high-current discharge of greater than 0.5 A.

2. The staged energy storage system of claim 1 wherein the first stage energy source means comprises a low-current battery having an output current of less than 10 mA and wherein the second stage energy source means is rechargeable so as to eliminate the need for a non-rechargeable, high-current battery.

3. The staged energy concentration system of claim 1 wherein the first stage energy source means comprises a non-rechargeable, high current battery having an output current of at least 1A and wherein the second stage energy source means is rechargeable so as to allow for the delivery of multiple closely spaced electrical countershocks within one second of each other.

4. The electrical circuit of claim 3 wherein the mean for selectively discharging allows for simultaneous connection of the first stage energy source means and the second stage energy source means to the transformer.

5. The staged energy storage system of claim 1 further comprising trickle charge control means electrically connected between the first stage energy source means and the second stage energy concentration means for controlling charging of the second stage energy concentration means.

6. The staged energy storage system of claim 5 wherein the trickle charge control means increases an output voltage of the first stage energy source means to supply a higher charging voltage to the second stage energy concentration means.

7. The staged energy storage system of claim 1 wherein the first stage energy source system is a low-current battery selected from the set comprising: a lithium iodide battery, a lithium carbon fluoride battery, a radioisotope-activated battery, a nuclear battery, or a thermo-electric battery

8. The staged energy storage system of claim 1 wherein the second stage energy concentration means is selected from the set comprising: a rechargeable battery, a double layer capacitor or an electrolytic capacitor.

9. The staged energy storage system of claim 8 wherein the rechargeable battery is comprised of one or more battery cells having a battery chemistry selected from the set comprising: a lithium battery, a NiCad battery, an alkaline battery, or a lead acid battery.

10. The staged energy storage system of claim 1 wherein the first stage energy source means is capable of delivering at least 1 W and the second stage energy concentration means stores at least 15 J.

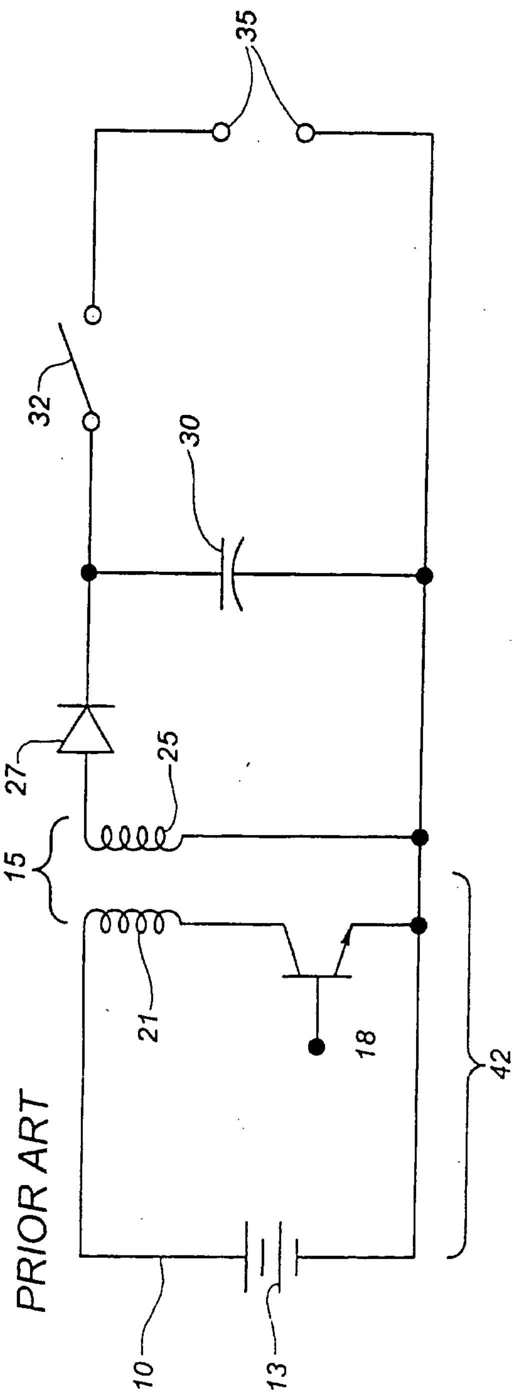


Fig. 1
PRIOR ART

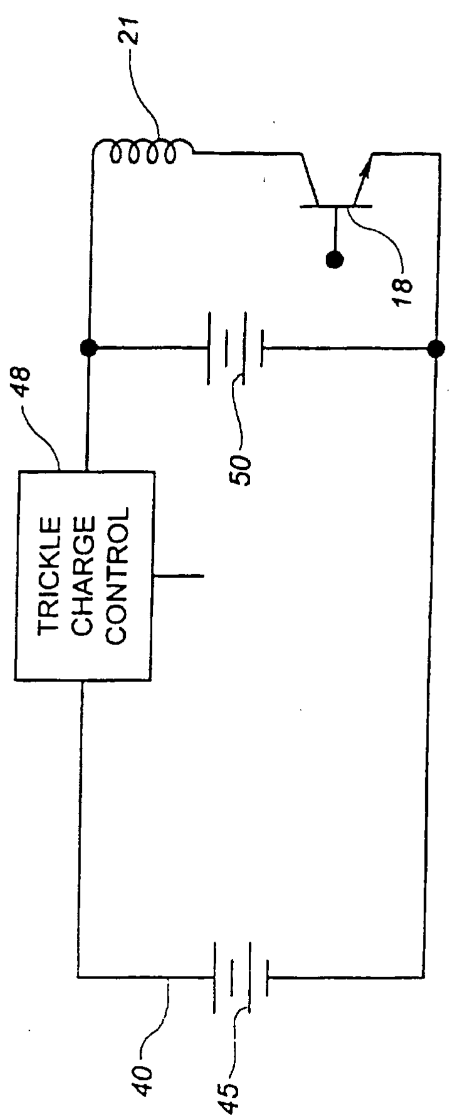


Fig. 2

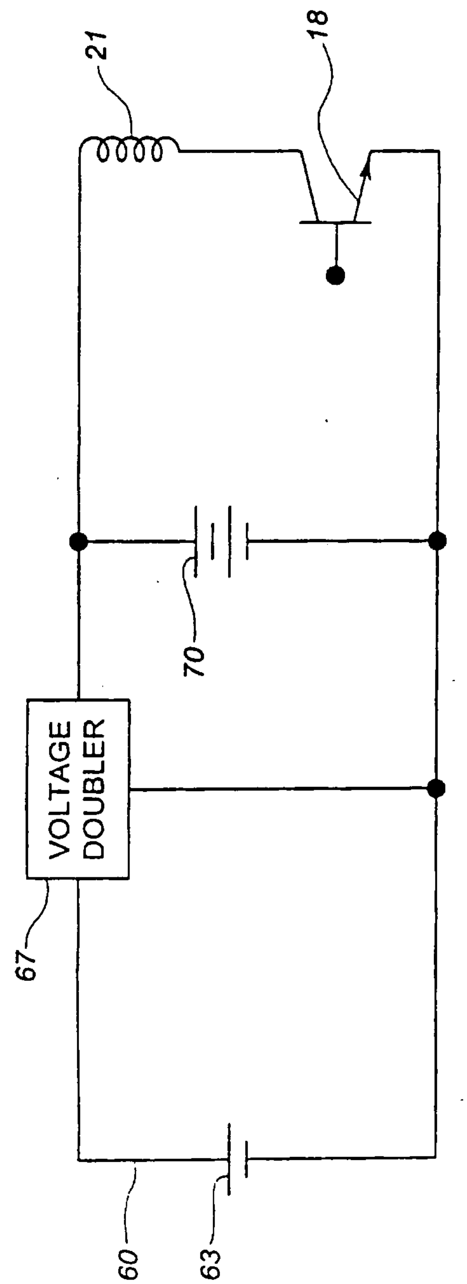


Fig. 3

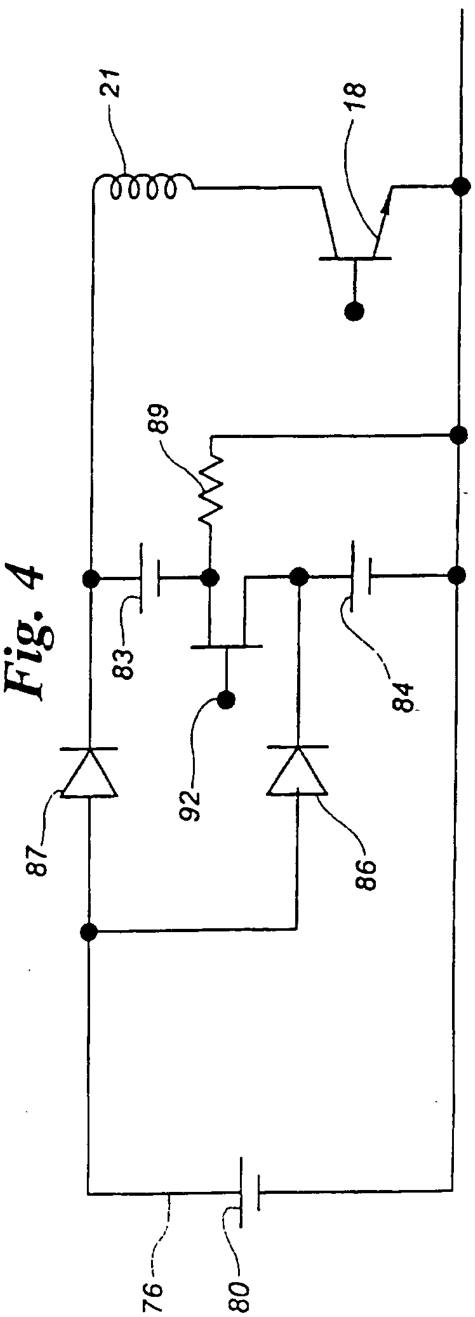


Fig. 4

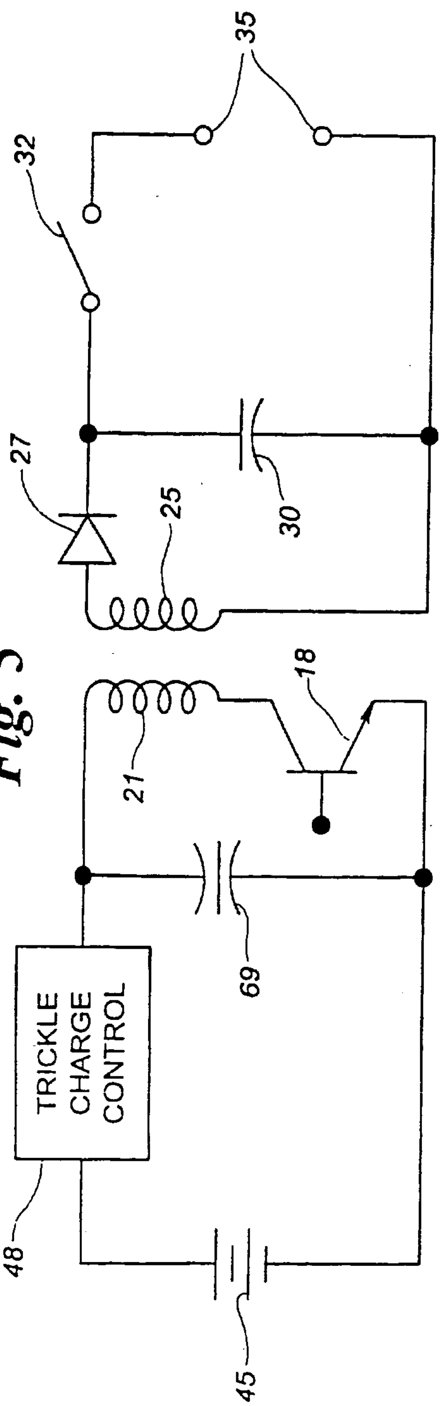

TRICKLE
CHARGE
CONTROL
48
45
69
21
18
25
27
30
32
35

Fig. 5

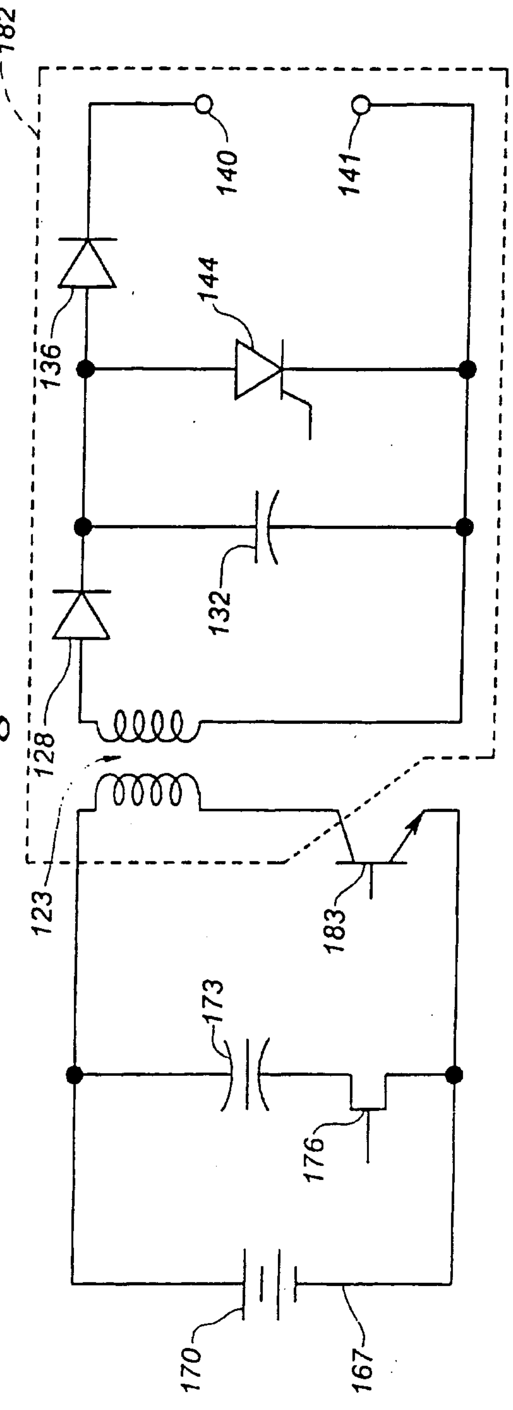
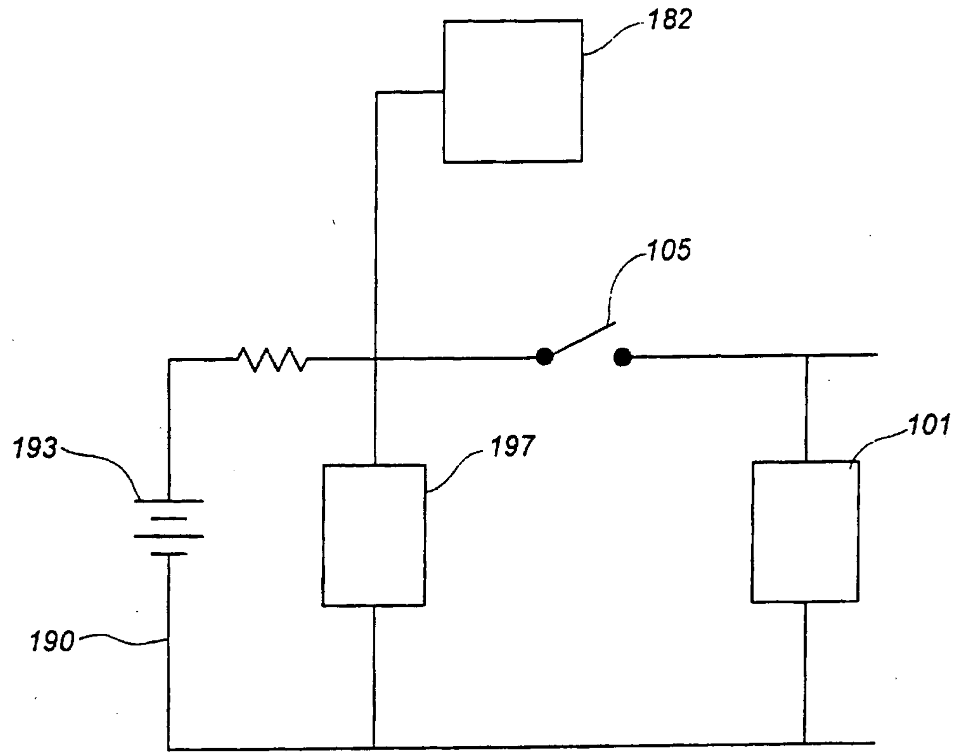

182
140
141
144
136
132
128
123
183
173
176
170
167

Fig. 6

Fig. 7



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/00763

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61N 1/39
US CL :607/5
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 607/5

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, P	US, A, 5,383,907 ,(KROLL) ,24 January 1995, see entire document.	1-10
X, P	US, A, 5,405,363 (KROLL ET AL.) 11 April 1995, see entire document.	1-10
X, P	US, A, 5,407,444 (KROLL) 18 April 1995, see entire document.	1-10

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

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